



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,902	01/16/2004	John R. Helland	A04P1003	8467
36802 7590 06/11/2007 PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER HOLMES, REX R	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,902	<b>Applicant(s)</b> HELLAND ET AL.	
	<b>Examiner</b> Rex Holmes	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-8 and 12-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-18 and 23-24 is/are allowed.
- 6) ☒ Claim(s) 2-8, 12-14, 19-21 and 25 is/are rejected.
- 7) ☒ Claim(s) 22 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/07 has been entered.

### ***Response to Arguments***

2. The Applicant argues that Thacker et al. does not disclose an adhesive module coupled to the proximal end of a lead body. Thacker et al. discloses an adhesive module (Fig. 2, 40; Col. 3, ll. 41-44) that is coupled to the proximal end of the lead through the lead body. Although the module is not located on the proximal end it is still coupled to the proximal end through the lead body. The Applicant further argues that Parry et al. does not require a reservoir module. As discussed below, The Thacker reference and the Parry reference are combined to form an obvious rejection. Thacker uses a channel and adhesive reservoir/module and Parry uses a two part light activated adhesive. Thacker discloses the claimed invention except for the radiation conduit, a two-part adhesive and a sheath that is rotatable around the body. Parry teaches that it is known to use radiation conduits, two-part adhesives and outer sheaths as set forth in Figs. 4 and 5 to provide a light-activated fixation means to more accurately affix a lead to tissue. It would have been obvious to one having ordinary skill in the art at the time

Art Unit: 3762

the invention was made to modify the lead fixation device as taught by Thacker, with the light activated fixation device as taught by Parry, since such a modification would provide the fixation device with a light activated adhesive for providing a more accurate and stronger way to affix electrodes to tissue.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 19 rejected under 35 U.S.C. 102(e) as being anticipated by Thacker et al. (U.S. Pat. 7,099,718 hereinafter "Thacker").

5. Regarding claim 19, Thacker discloses a lead fixation device that includes a lead (Fig. 2, Element 15), a conductor (Fig. 2, Element 26), a plurality of electrodes (Fig. 2, Elements 24), a channel(s) to deliver adhesive to a nerve (Fig. 2, Elements 22, 27; Fig. 3, Elements 22, 25, 27), and an adhesive reservoir (Fig. 2, 40; Col. 3, ll. 41-44).

Thacker further discloses that the channel is adjacent to the electrodes and that it dispenses adhesive between the electrode and tissue at an opening on the side of the lead (Fig. 2).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 5, 12-14, 20-21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thacker as applied to claim 19 above, and further in view of Parry et al. (U.S. Pat. 6,718,212 hereinafter "Parry").

9. Thacker discloses a lead fixation device that includes a lead (Fig. 2, Element 15), a conductor (Fig. 2, Element 26), a plurality of electrodes (Fig. 2, Elements 24), a channel(s) to deliver adhesive to a nerve (Fig. 2, Elements 22, 27; Fig. 3, Elements 22, 25, 27), and an adhesive reservoir that is coupled to the proximal end through the lead (Fig. 2, 40; Col. 3, ll. 41-44). Thacker further discloses that the channel is adjacent to the electrodes and that it dispenses adhesive between the electrode and tissue at an

Art Unit: 3762

opening on the side of the lead (Fig. 2), but Thacker fails to disclose a radiation conduit, a two-part adhesive and a sheath that is rotatable around the body. However, Parry discloses a light activated adhesive fixation method that allows for UV radiation to pass through a conduit to the fixation site to harden a one-part or two-part adhesive (Fig. 4, Elements 68, 54, 56; Col. 5, ll. 63-67 & Col. 6, ll. 1-2). Parry further discloses that a sheath encloses the multi-lumen core and is rotatable around the core (Figs. 4 & 5, Elements 68, 60, 46, 70, 56).

10. Regarding claims 2, 5, 12-14, and 20, Thacker discloses the claimed invention except for the radiation conduit, a two-part adhesive and a sheath that is rotatable around the body. Parry teaches that it is known to use radiation conduits, two-part adhesives and outer sheaths as set forth in Figs. 4 and 5 to provide a light-activated fixation means to more accurately affix a lead to tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead fixation device as taught by Thacker, with the light activated fixation device as taught by Parry, since such a modification would provide the fixation device with a light activated adhesive for providing a more accurate and stronger way to affix electrodes to tissue.

***Allowable Subject Matter***

11. Claims 15-18 and 23-24 are allowed.

12. Claims 22 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes  
Examiner  
Art Unit 3762



George Evanisko  
Primary Examiner  
Art Unit 3762

6/7/7